



Office Action Summary

Application No. 08/969,046	Applicant(s) Chiang et al.
Examiner Ousama Zaghmout	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.

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Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on declarations: 11/27/2000, 03/19/2001, 04/30/2001. CPA: 04105/2001
 4 Amendments:
 03/19/2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-38 and 41-48 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-38 and 41-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 37,34
- 18) Interview Summary (PTO-413) Paper No(s). _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: Notice Reg. Seq. Requirement.



Application Serial Number: 08/969,046
Art Unit: 1638

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Status of Application

1. The request filed on 04/05/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/969,046 is acceptable and a CPA has been established. An action on the CPA follows.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The amendment filed 03/19/2001 has been received and entered (Paper No. 36).
4. Status of the claims:

Claims 41-48 have been newly added (Paper No. 36).

Claims 1-38, 41-48 are pending.
5. A copy of the signed IDS (1149 form) is enclosed. The contents of Patent Numbers: 5,850,020 and 5,952,486 have been acknowledged by the Examiner of record.
6. The declarations submitted under 37 CFR 1.131 have been received and filed (Paper Nos. 29, 35 and 37).
7. The rejection under 35 USC 103(a) over Kajita et al taken with Huang et al has been withdrawn in view of the 1.131 Declaration filed 11/27/2000. The Examiner of the record has confirmed has ~~the~~ that the Kajita et al reference was not available until the beginning of 1997 and hence that it is 102 (a) type reference. Therefore, the 1.131 Declaration serves to overcome the rejection under 103(a).

Sequence Rules

8. This application contains sequence disclosure that are encompassed by the definitions for nucleotide and/or amino acid sequence set forth in 37 CFR 1.82 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there are sequences listed in the specification that do not comply with the sequence rules (e.g., pages 8, 11, 12, and 29). They need to be identified by SEQ ID NO. A CRF which contains all the sequences needs to be submitted along with a paper copy.

Full compliance with the Sequence Rules is required in response to this Official action. A complete response to this Official action should include both compliance with the Sequence Rules and a response to the issues set forth below. Failure to comply with both of these requirements in the time period set forth in this Official action will be held to be non-responsive.

Claim Rejections-35USC 112

Ist Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

I. Written description:

Claims 1-38, 41-48 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention which would reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The claims are generically drawn to a method of altering a characteristic of a plant with a nucleotide sequence encoding 4CL or with a nucleotide sequence that has at least a 60% sequence identity to a nucleotide sequence encoding 4CL or at least about 60% sequence identity to SEQ ID NO.1 or 3 but the specification discloses only the nucleotide sequences of SEQ ID Nos: 1 or 3. The specification fails to describe adequate representative species of the nucleotide sequence encompassed by the claims by their relevant identifying characteristics, e.g. by sequence or other structure or properties. At the time the application was filed, one of skill in the art could not have predicted the relevant identifying characteristics of the antisense nucleic acids based only on the sequences of SEQ ID NO:1 and 3. Accordingly, one of skill in the art would not have recognized the applicant to have been in possession of the claimed antisense nucleic acids at the time the application was filed.

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

II. Scope of enablement:

Claims 1-38, 41-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of production a

transgenic tree by transformation with the nucleotide sequence of SEQ ID NOs: 1 or 3, does not reasonably provide enablement for the production of a transgenic tree by transformation with any nucleotide sequence encoding a p-coumarate co-enzyme A ligase (4CL). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims are drawn to a method of altering a characteristic of a plant with a nucleotide sequence encoding 4CL, or with nucleotide sequence that has at least a 60% sequence identity to 4CL (the Examiner assumes that Applicants' intention is: at least 60% sequence identity to a nucleotide sequence encoding 4CL because one can not compare a nucleotide sequence to an amino acid sequence) or at least about 60% sequence identity to SEQ ID NO.1 or 3. The specification, while being enabling for the isolation of Seq ID NOs 1 and 3 from aspen, does not reasonably provide enablement for the isolation of other nucleotide sequences that encode 4CL or that have with 60% sequence identity to the either a nucleotide sequence encoding 4Cl or SEQ ID NO:1 or 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification discloses the identification and characterization of a cDNA from aspen encoding a 4CL protein with Seq ID NOs 2 and 4, the cDNA comprising Seq ID Nos 1 and 3. It would be an undue burden for one of skill in the art to practice the claimed invention in terms of making all the variants of 60% of the disclosed sequences as claimed, because the specification provides no guidance as to the many different variants that can be produced. Also, undue experimentation would be required to screen through the myriad of cDNA and genomic sequences from any organism to identify those that are structurally and functionally related to SEQ ID NO:1 or 3, and also encode 4CL and/or can be used in the claimed method.

It is well known in the art that minor modification in protein sequence can have major differences in protein activity, conformation, antigenicity and so forth, and hence the effects of sequence changes a protein function is highly unpredictable. A sequence with 60% identity to SEQ ID NO:1 encompasses any sequence that has 40 out of 100 nucleotide differences. These differences can be arranged contiguously or sparsely at different positions on a sequence. There is no guidance in the specification to teach where the sequence could be substituted, without affecting the functionality of the encoded protein.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use the invention as claimed. Therefore, undue experimentation would be required to enable the claims.

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 12, 23, 31, 41-42 and dependent claims 2-10, 13-22, 24-30, 32-38, 43-48 are rejected under 35 USC 112, second paragraph, as being vague and indefinite as it is not clear what “altered lignin structure means”. It is not clear if Applicants mean the physical or the chemical structure of lignin or means an increase or decrease in certain intermediates in the lignin pathway or some other meaning. A clarification is requested.
2. Claims 1, 8, 12, 19-21, 23, 31, 41-42 and dependent claims 2-7, 9-11, 13-18, 22, 24-30, 32-38, 43-48 are rejected under 35 USC 112, second paragraph, as being vague for the recitation of the words “altered” and/or “altering” as it is not clear whether altering or altered means an increase or decrease or some other unknown meaning.
3. Claims 41-42 and dependent claims 43-48 are rejected under 35USC 112, second paragraph, as being vague for the recitation of the phrase “does not receive the nucleotide sequence”. Replacement of said phrase with --is not transformed with said nucleotide sequence-- would obviate the rejection.
4. Claims 41-42 and dependent claims 43-48 are rejected under 35USC 112, second paragraph as being indefinite for the recitation of “60% sequence identity to 4CL” because one can not compare a nucleotide sequence to an enzyme (4CL).

Conclusion

No claims are allowed.



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Future Correspondence

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell Ph.D., can be reached on (703) 308-4310. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

June 28, 2001

Amy Nelson
AMY J. NELSON, PH.D
PRIMARY EXAMINER